

## **REMARKS**

### **I. Status of the Claims**

Claims 31-34 are pending and under examination. Claim 35 is withdrawn from consideration as being drawn to a non-elected invention, but may be rejoined upon allowance of the product claims.

### **II. Objection to the Specification**

In the Action, the Examiner objected to the specification because the first page of the specification allegedly does not list all the applications to which the priority claim has been claimed.

Applicants have amended the first page of the specification to update the priority claims as requested by the Examiner, thereby obviating this ground of objection to the specification.

### **III. Rejection for Double Patenting Acknowledged**

Applicants acknowledge the provisional rejection of claims 31-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of co-owned, co-pending U.S. Application No. 12/182,818, and will file any necessary terminal disclaimer upon notification of allowable subject matter in this or the co-pending application.

### **IV. Rejection of claims 31-34 under 35 U.S.C. §102(b) as assertedly anticipated by Amalfitano should be withdrawn**

In the Action, the Examiner rejected claims 31-34 under 35 U.S.C. §102(b) as allegedly anticipated by Amalfitano et al. (Genetics in Medicine 3:132-38, 2001) (hereinafter "Amalfitano"). The Examiner alleged that Amalfitano discloses "a composition comprising rhGAA purified from rhGAA secreting Chinese hamster ovary (i.e., CHO) cells. Said rhGAA was administered to the patients suffering from a lysosomal disease. Thus, said

composition comprised a pharmaceutically acceptable carrier, diluent or excipient.” (Page 4 of the Action). Although the Examiner acknowledges that Amalfitano is silent regarding the rhGAA’s specific properties (page 4 of the Action), the Examiner asserted that “Amalfitano et al., anticipate said subject matter and said features described in claims 31-33 because the rhGAA that Amalfitano administers to said patients is the same component as is instantly claimed and would therefore inherently have the properties that are in instantly claimed claims 31-33...” The Applicants respectfully disagree.

M.P.E.P. (§2112(IV)) states, “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). In the present case, the Examiner has failed to establish inherency because the evidence in Amalfitano and in the prior art does not show that the claimed rhGAA’s specific properties are necessarily present in the rhGAA described in Amalfitano, i.e., the art does not “make clear” that the claimed properties are present as required by MPEP 2112. In particular, the rhGAA of Amalfitano lacks at least one of the specific properties of the claimed rhGAA’s as described below.

*Producing rhGAA with the specific property recited in part (b) of claim 31 was not achieved in Amalfitano using the methods described therein.*

As acknowledged by the Examiner, Amalfitano did not describe the specific properties of the rhGAA that was used in the phase I/II clinical trial for Pompe Disease (page 4 of the Action). In describing the purification of the rhGAA, Amalfitano (page 133, 2<sup>nd</sup> col.) cites to the purification method of Van Hove et al., *Proc. Natl. Acad. Sci. USA* 93:65-70, 1996 (cited in Applicants’ IDS filed 10/03/2008), describing the source of rhGAA as “purified from rhGAA secreting CHO cells constructed as previously described,” i.e., as in Van Hove. Van Hove et al. is also silent regarding the specific properties of the rhGAA purified from rhGAA secreting CHO cells, however, the enzyme purified in Van Hove et al. was analyzed and used in a comparative study in Canfield, U.S. Pat. No. 6,537,785 (cited in Applicants’ IDS filed 10/03/2008). At column 20, lines 19-32, Canfield states that the Van Hove et al. rhGAA was obtained and analyzed, and “showed that less than 1% of the

oligosaccharides contained any M6P and bis-phosphorylated oligosaccharides **were not detectable**" (emphasis added). Example 27 of Canfield (column 37, lines 24-63) specifically discloses the results of tests on the Van Hove et al. rhGAA, *i.e.*, Rh-GAA (Secreted), finding that 1% of the enzyme contained mannose-6-phosphate (1M6P), and no bisphosphorylation (2P-Gn) was detected. One mole percent (or .01 moles) of M6P per mole of protein, as well as no detectable bis-phosphorylation of the protein, fails to meet the properties of the claimed rhGAA as recited in part (b) of claim 31, reciting at least 0.7 moles of bis-phosphorylated oligomannose per mole of protein. Thus, the rhGAA of Amalfitano, produced in the same manner as the Van Hove protein, lacks the characteristics of the claimed GAA.

As the examiner acknowledges, the art is silent about the properties of the art rhGAA with respect to the properties of the rhGAA recited in the claims. Because the cited art does not recite each and every feature recited in the present claims (see, e.g., claim 31 (b)), Amalfitano does not describe a rhGAA that inherently has the same features as the claimed invention. Accordingly, Applicants respectfully submit that the rejection of the claims under 35 U.S.C. §102(b) as allegedly anticipated by Amalfitano should be withdrawn.

## V. Conclusion

Applicants submit the application is in condition for allowance and respectfully request notification of the same.

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Respectfully submitted,

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